Application No. 08/974,584

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 CFR 1.821 - 1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e).

☐ 7.

Other: _____

Applicant must provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing"

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d)

For questions regarding compliance with these requirements, please contact:

For Rules Interpretation, call (703) 308-1123
For CRF submission help, call (703) 308-4212
For PatentIn software help, call (703) 557-0400

Joni R. Schenier

JONI R. SCHENIER
PRIMARY EXAMINER
GROUP 1600

Please return a copy of this notice with your response.

DETAILED ACTION

Sequence Requirements

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821 (a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reasons set forth on the attached **Notice To Comply With Requirements For Patent Applications Containing Nucleotide And/Or Amino Acid Sequence Disclosures**.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, 40, 47, 49-51, 67-69, 74-90, 92 and 94-104, drawn to telomerase reverse transcriptase (TRT) proteins, variants and fragments of the proteins; TRT and telomerase RNA complexes; methods of preparing complexes of TRT and telomerase RNA; and pharmaceutical compositions containing TRTs, classified in class 530, subclass 350 and class 424, subclass 184.1.

II. Claims 11-18, 36, 37, 40-43, 47, 52-65, 70-73, 91 and 93, drawn to polynucleotides encoding TRTs, variants or fragments; hybridization assays for the detection of polynucleotides encoding TRT, variants or fragments; expression

vectors; host cells; and pharmaceutical compositions, classified in class 536, subclasses 23.1 and 24.31; class 435, subclass 6; and class 514, subclass 44.

III. Claims 25-32, drawn to transgenic animals, classified in class 800, subclass 18.

IV. Claims 33-35, 40-43, 47 and 66, drawn to antibodies specific for TRTs; detection assays using the antibodies; and pharmaceutical compositions containing the antibodies, classified in class 530, subclass 387.9, and class 435, subclass 7.1.

V. Claims 38 and 39, drawn to screening assays for the detection of compounds which modulate TRT activity, classified in class 435, 4.

VI. Claim 44, drawn to a method of increasing the proliferative capacity of vertebrate cells in vitro by increasing expression of TRT - classification cannot be determined without further information.

VII. Claims 45 and 46, directed to the use of an unspecified agent which increases expression or activity of telomerase in the manufacture of a medicament - classification cannot be determined without further information.

VII. Claim 48, directed to the use of an unspecified agent which inhibits expression or activity of telomerase in the manufacture of a medicament - classification cannot be determined without further information.

The inventions are distinct, each from the other because of the following reasons:

The proteins of Group I, the nucleotides of Group II, the transgenic animals of Group III, and the antibodies of Group IV represent separate and distinct inventions, as they are made by, and used in, separate methods; moreover, the search required for one group is not required for the other. The various detection and diagnostic methods of Group II are separate and distinct from the detection methods of Group IV, and from the screening methods of Group V, as they require different reagents and protocols, and have different outcomes.

Similarly, the method of Group VI (directed to enhancing the proliferative capacity of a cell) is separate and distinct from the methods of Groups VII or VIII (directed to making medicaments which enhance or inhibit TRT) as the methods require different reagents and protocols, and have different outcomes. The methods of Groups III and IV represent invention separate and distinct from the methods of Groups I and II for the same reasons.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

A telephone call was made to Randolph T. Apple on September 18, 1998, but did not result in an election being made.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is (703) 305-3704, and a Fax cover sheet is attached to this office action for your convenience. We encourage your participation in this pilot program. If you have any questions or suggestions please contact Donald E. Adams, Supervisory Patent Examiner, at Donald.Adams@uspto.gov or (703) 308-0570. Please limit the use of this dedicated Fax number to responses to Written Restrictions. Thank you in advance for allowing us to enhance our customer service.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Toni R. Scheiner whose telephone number is (703) 308-3983. The examiner can normally be reached Monday-Friday from 8:30 to 5:00.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

9/29/98

Joni R. Scheiner

TONI R. SCHEINER
PRIMARY EXAMINER
GROUP 1600